ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 700 and 723

[OPPTS-50596; FRL-3890-4]

RIN 2070-AC14

Premanufacture Notification Exemption; Revision of Exemption for Chemical Substances Manufactured in Quantities of 1,000 Kilograms or Less Per Year; Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires that persons notify EPA before they manufacture or import a new chemical substance for commercial purposes. Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule to exempt the manufacturer or importer of any new chemical substance from the provisions of section 5 if the Agency determines that the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk of injury to health or the environment. EPA is proposing to amend the current TSCA section 5(h)(4) limited exemption defined at 40 CFR 723.50 for persons who manufacture certain chemical substances in quantities of 1,000 kilograms or less per year. This proposed amendment would increase the volume limit to 10,000 kilograms or less a year. Also, this notice proposes to add a new section 5(h)(4) exemption category for certain chemical substances with low environmental releases and human exposures. To ensure that these chemical substances will not present an unreasonable risk, EPA has included procedural safeguards, including a 30-day review, and other conditions in the exemption.

DATES: Comments must be received by April 9, 1993. If requested, EPA will conduct public hearings on the proposed rule amendments. Requests to make an oral presentation must be received by April 9, 1993.

ADDRESSES: All comments and requests to speak at the public hearing must be sent to: TSCA Document Control Office (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, DC 20460, (Phone: 202-260-1532).

Comments should include the docket control number. The docket control number for this amendment is OPPTS-50594. Since some comments may contain confidential business information (CBI), all comments must be sent in triplicate (with additional sanitized copies if CBI is involved). Comments on this proposed rule will be placed in the rulemaking record and will be available in the TSCA Public Docket Office, Rm. NE-G-004 at the above address between 8 a.m. and 12 noon and 1 p.m. and 4 p.m., Monday through Friday, excluding public holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543-B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

Electronic Availability: This document, along with three other related documents, OPPTS-50593, 50594, and 50595, is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the **Federal Register**. By modem dial (202) 512-1387 or call (202) 512-1530 for disks or paper copies. This document and the three related documents are available in Postscript, Wordperfect, and ASCII.

The exemption for chemical substances manufactured in quantities of 1,000 kilograms or less per year became effective on August 26, 1985. The supporting rationale and background for that exemption were published at 50 FR 16477, April 26, 1985 and 47 FR 33896, August 4, 1982. While general background information is presented here, readers should also consult the preambles for those notices for further information on the objectives and rationale for the rule and the basis for the TSCA section 5(h)(4) "will not present an unreasonable risk" finding.

I. Background

A. Authority

Section 5(a)(1) of TSCA (15 U.S.C. 2604 (a)(1)) requires any person who intends to manufacture or import a new chemical substance to notify EPA 90 days before manufacture or importation begins. Section 5(h)(4) of TSCA (15 U.S.C. 2604 (h)(4)) allows the Administrator, by rule, to grant an exemption from any or all of the requirements of section 5 if he or she determines that the manufacture, processing, distribution, use, or disposal of a substance will not present an unreasonable risk of injury to health or the environment.

B. History

In early 1981, EPA received a petition from the Chemical Manufacturers Association (CMA) requesting exemptions from certain provisions of section 5 of TSCA for: (1) Site-limited intermediates; (2) chemical substances produced in quantities of 25,000 pounds or less per year; and (3) polymers whose precursor monomers are on the TSCA Inventory. On August 4, 1982, EPA proposed regulations for site-limited intermediates and for chemical substances produced in quantities of 1,000 and 10,000 kilograms or less per year (47 FR 33920). Also on April 4, 1982 (47 FR 33924), EPA proposed regulations for exempting certain polymers, and promulgated final regulations on November 21, 1984 (49 FR 46066). Final regulations for chemical substances produced in quantities of less than 1,000 kilograms per year were promulgated by the Agency on April 26, 1985 (50 FR 16477). Based on public comments, and the requirements under section 5(h)(4) of TSCA, the Agency decided to exempt only chemical substances produced in quantities of 1,000 kilograms or less per year from full section 5(a)(1) premanufacturing review. The Agency determined that it could not exempt site-limited intermediates or the 10,000 kilograms category chemical substances without requiring certain procedural safeguards designed to ensure low risk, such as requiring manufacturers to obtain a qualified expert review of their exemption application prior to submission. Industry commenters stated these procedural safeguards were overly burdensome. EPA decided it could not reduce those safeguards given its level of experience in 1985 and still make the required section 5(h)(4) findings that activities associated with the exempted chemical substance would not present an unreasonable risk.

In the 8 years since the low volume exemption was promulgated, EPA has enhanced its technical assessment capabilities considerably. For example, in searching for chemical analogues to assist in the review of the potential toxicity of a new chemical substance, the Agency is now able to perform automated chemical substructure searches. EPA toxicologists can now, as a result, quickly locate available toxicity data on chemicals with reactive substructures analogous to those of the new substances under review. With this and other enhancements to the review process developed since the new chemicals program began in 1977, the Agency believes that the production volume ceiling for the low volume

exemption can now be raised to 10,000 kilograms or less per year and that a new exemption for low release and exposure chemicals can be promulgated without compromising the Agency's ability to identify and protect against substances that may present an unreasonable risk of injury to human health or the environment.

For a more extensive review of the history of the low volume and the site-limited intermediate exemptions, please refer to the **Federal Register** notices cited earlier in Unit I. of this preamble.

II. Discussion of the Proposed Amendments

1. *Chemical substances manufactured at 10,000 kg or less per year.* The Agency is proposing that manufacturers of all chemical substances manufactured in quantities of 10,000 kilograms or less per year will be eligible to apply for a new exemption category. (Note that throughout 40 CFR parts 721 and 723, the term "manufacturer" is defined in TSCA section 3(8), 15 U.S.C. 2602(8), to include persons who import the specified chemical substance, and the term "manufacture" is defined to include importation.) Upon approval, manufacturers will be permitted to manufacture up to 10,000 kilograms during every 1–year period beginning on the date of review period expiration.

As with the current exemption, chemical substances will not be approved under the exemption if the Agency believes that they or their reasonably anticipated metabolites, environmental transformation products, byproducts, or impurities raise a concern for serious acute or chronic human health effects or significant environmental effects under reasonably anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal. Any submitted exemption notice will be denied if the Agency is unable to affirmatively find that manufacture, processing, distribution, use, and disposal of the exempted substance will not present an unreasonable risk of injury to human health or the environment.

The proposal provides that manufacturers requesting this exemption must submit notices 30 days prior to commencement of manufacture or import. EPA believes that the extra 9 days over the current 21–day review period will be needed to perform risk assessments for the increased number of submissions received under this expanded low volume exemption and the low release and exposure exemption category described below.

Also in keeping with the current exemption, where manufacturers provide information on human exposure controls or environmental release controls to support the exemption notice, the manufacturers must maintain those controls throughout the duration of the exemption. Exemption notices containing inadequate human exposure or environmental release controls may be conditionally denied until the submitters provide sufficient information regarding exposure controls. Manufacturers are also bound to the manufacturing sites and uses approved in their exemptions.

The Agency is proposing to modify the restriction that only one low volume exemption holder be allowed for any given substance. Under the proposal, subsequent manufacturers of a substance for which one manufacturer already holds an exemption will be permitted to submit an exemption notice; however, subsequent manufacturers must, in addition to the normal requirements, affirmatively demonstrate that approval of their exemptions will not result in additional environmental releases and human exposures which, in the aggregate, will undermine the Agency's previous determination that the manufacturing, processing, and use of the low volume substance will not present an unreasonable risk of injury to human health or the environment. Subsequent manufacturers unable to make this affirmative showing will be required to submit either a full premanufacture notice or an application under another exemption prior to commencement of commercial manufacture. To prevent companies from applying for an exemption merely to preclude a potential competitor's exemption, the Agency is proposing to require submitters to certify that they will commence commercial manufacture of the chemical substance under the exemption within 1 year of the expiration of the review period. This certification must accompany submission of the exemption notice. If manufacture does not commence within 1 year, the submitter must withdraw the exemption in writing within 1 year of the expiration of the review period.

In accordance with current practice under the present 1,000 kilogram exemption, the Agency will generally perform the risk assessment under the new exemption as if the total amount permissible under the exemption (10,000 kgs) were being produced. However, EPA is proposing to permit submitters wishing their exemptions to be reviewed based upon annual production volumes lower than 10,000 kilograms to so indicate in their initial exemption notice. Submitters who so elect, however, would be bound by their election. Submitters who subsequently wished to increase their maximum production volume under the exemption would be required to submit a new exemption notice and cross-reference the original exemption number on the cover of the notice. If the new exemption is granted, it would supersede the previous exemption.

Regarding the transition period between the existing and proposed exemption, the Agency will continue to accept exemption notices under the terms of the current 1,000 kilogram or less exemption category until the final rule altering this exemption category becomes effective. At that time, the existing 1,000 kilogram exemption category would no longer be available. All exemptions previously granted under the 1,000 kilogram exemption will remain binding and effective under the superseded provisions of 40 CFR 723.50 even though such provisions will no longer be contained in the Code of Federal Regulations; however, the proposed exemption does not contain a separate 1,000 kilogram or less category. A manufacturer or importer who was granted an exemption under the prior 1,000 kilogram per year or less exemption will be allowed to submit a new exemption notice to increase the production volume up to 10,000 kilograms per year for the same chemical substance. If a manufacturer does apply for the 10,000 kilogram exemption, its notice will be reviewed for unreasonable risk at the increased production volume. A new risk assessment will be performed based on the information submitted in the new notice. A submitter of a subsequent 10,000 kilogram exemption will be allowed to continue to manufacture under the terms of the 1,000 kilogram exemption until a regulatory decision is made on the new exemption notice. If the new notice is granted, it will supersede the 1,000 kilogram exemption.

2. *Low release and exposure chemicals.* In connection with the Agency's overall pollution prevention strategy, EPA is proposing to add a new exemption category for chemical substances with low environmental releases and low human exposures during their manufacture, processing, and use. All manufacturers and importers of new chemical substances subject to PMN requirements meeting the stated release and exposure criteria would be eligible to apply for this low release and exposure (LoREX) exemption, regardless of production volume. The LoREX exemption is intended to encourage companies to

develop manufacturing, processing, and use techniques which minimize exposures to workers, consumers, the general public, and the environment.

As with the low volume exemption, the Agency is proposing to require that the uses and manufacturing sites be restricted to those approved in the exemption notice, and that submitters also be bound to the approved release and exposure controls. EPA believes that these binding provisions of the LoREX exemption will, in many instances, prove to be an effective substitute to regulation under section 5(e) of TSCA. Thus, EPA expects this new exemption category to significantly reduce the administrative costs presently devoted to section 5(e) consent order development and review, and to permit manufacturers to commence commercial production of their new products more quickly, while ensuring against unreasonable risk to human health or the environment.

Potential submitters should be mindful that the principal focus of this exemption is on release and exposure, not toxicity. In light of this, the Agency will apply the release and exposure criteria strictly, and, although it will consider any relevant toxicological data submitted, it will be unable to conduct a thorough review of that data in many cases within the 30–day review period. A primary goal of this exemption is to minimize the time and resources required to review new chemical substance submissions; to the extent that the Agency must undertake detailed examination of the inherent toxicity of a given chemical substance, that goal is compromised and a PMN notice would be more appropriate.

To satisfy the required section 5(h)(4) findings of unreasonable risk, the submitter would first have to meet the eligibility criteria in the following Table 1 indicating that exposure to the substance, and hence the risk presented by the substance, is low:

TABLE 1.—PROPOSED LOW RELEASE/EXPOSURE (LOREX) ELIGIBILITY CRITERIA[1]

Type of Exposure or Release	Eligibility Criteria for Exemption
Human Exposure	
General Population Exposure.	
Dermal:	None
Inhalation:	None[2]
Drinking Water:	<1 mg/yr[3]
Consumer Exposure.	
Dermal:	None
Inhalation:	None
Worker Exposure.	
Dermal:	None
Inhalation:	None, unless adequate protection provided
Environmental Release	
Ambient Surface Water Releases.	No releases resulting in surface water concentrations above 1 ppb[4]
Ambient Air Releases	No incineration releases above 1 µg/m³ maximum annual average concentration [5]
Land/Groundwater Releases.	No releases to landfill unless submitter demonstrates that the exempted substance has negligible ground-water migration potential

[1] This table lists the minimum criteria required to apply for the exemption. Based on the review of the notice, lower concentrations may be required by the Agency for substances with potential for carcinogenic, neurotoxic, or other effects.
[2] No inhalation exposure permitted except as provided under the ambient air incineration criteria.
[3] Estimated average dosage resulting from drinking water exposures in streams with maximum allowable concentration permitted under ambient surface water criteria (1 ppm).
[4] Concentration to be calculated using methods prescribed in 40 CFR 721.90.
[5] Using following formula: (kg/day release after treatment) X (release days/year) X 9.68 X 10⁶ µg/m³.

To satisfy the human exposure side of the eligibility criteria, the submitter would have to show that there are no exposures to consumers or the general public (except as provided under the surface water and ambient air criteria) inherent in the proposed manufacturing, processing, or uses of the substance, and that any worker exposure which is likely to occur will be adequately controlled through use of engineering controls, work practices, and/or personal protective equipment.

In terms of environmental releases, LoREX eligibility criteria for releases to three environmental media are proposed. In assessing the potential for environmental release, the submitter should consider all routine releases from manufacture, processing, and use, including releases associated with cleaning of equipment and from disposal or cleaning of containers and packaging. For ambient surface water, the Agency is proposing that submitters either (1) prevent all direct and indirect releases of the exempted substance to surface waters; or (2) demonstrate that any releases to water that may occur will result in surface water concentrations of the substance that are no greater than 1 part per billion (ppb) using the surface water concentration calculation method described in 40 CFR 721.90. Based on Agency worst case assumptions for drinking water exposure estimates, surface water concentrations of 1 ppb will result in human drinking water exposures at or below the 1 mg/ysar LoREX drinking water criteria in nearly every case; therefore, compliance with the drinking water exposure criteria will be presumed from compliance with the 1 ppb surface water level. The Agency will reserve the right, however, to require lower surface water concentrations on a case-by-case basis when concerns for carcinogenicity, neurotoxicity, or other serious chronic effects are raised, or under conditions where actual drinking water exposures are likely to significantly exceed the 1 mg/yr dosage.

The proposed LoREX eligibility criterion for maximum annual average ambient air release concentration from incineration is 1 µg/m³. This level was derived from air exposure modeling estimates of maximum ground level concentrations from incinerator stacks, using worst case meteorological data sets. To determine whether a particular substance meets the criteria, submitters would calculate exposure levels using the method described in Table 1. As with drinking water exposures, the Agency may require lower air release levels in individual cases if concerns for chronic health effects are raised for the exempted substance.

For land/groundwater disposal, EPA is proposing that LoREX substances not be disposed of by landfill or other land disposal methods unless the submitter demonstrates that the groundwater migration potential of the substance is negligible. To make such a demonstration, a submitter will be required to provide data on the biodegradation and leaching potential of the exempted substance, or other data which clearly establishes that significant releases to groundwater will not occur. EPA suggests the following core set of tests to establish groundwater migration potential:

(a) An inherent biodegradability in soil test (40 CFR 796.3400).

(b) An anaerobic biodegradability of organic chemicals test (40 CFR 796.3140).

(c) Depending on the substance's chemical properties, either a sediment and soil adsorption isotherm test (40 CFR 796.2750) or a soil adsorption isotherm test (40 CFR 796.2700).

Although it is difficult to state in advance precisely what combinations of results from the above testing would clearly establish that the groundwater migration potential of a chemical substance is "negligible", some broad parameters may be given. For example, manufacturers who perform soil adsorption testing that result in values

for the logarithm of the soil adsorption coefficient ("log K_{oc}") of their new chemical substances of 4.5 or greater will generally be found to have satisfied the "negligible groundwater migration potential" standard, unless persistent in the environment. Similarly, biodegradation test data demonstrating half-lives of chemical substances of under 1 week, or complete degradation in under 2 weeks, would satisfy the LoRex criterion in most instances. Hydrolysis data showing that a chemical substance hydrolyzes at a rapid rate would also generally be accepted by the Agency. Chemical substances which do not show either a 4.5 or greater Log K_{oc} value alone or a half-life of under 1 week alone may nonetheless qualify for the LoRex exemption if the two values in combination, or together with other relevant data, support a conclusion that significant amounts of the substances will not reach aquifers.

EPA invites public comment on this and other generic criteria which might be useful in the groundwater migration determination. The Agency also intends to continue encouraging initiation of any testing. Such consultation frequently results in more relevant data and can often lower the submitters' test costs. Upon approval of a LoREX exemption, the submitter would be bound to the continuous use of the exposure and release controls described in the approved exemption, as well as the listed uses and manufacturing sites. The Agency will deny an exemption notice notwithstanding satisfaction of the exposure-based exemption criteria if it believes it cannot support the affirmative finding required under section 5(h)(4) of TSCA that the manufacture, processing, distribution, use, and disposal of the chemical substance, under the conditions described in the notice, will not present an unreasonable risk to human health and the environment.

EPA solicits comment on whether the LoRex exemption criteria are set at a reasonable level to allow new chemical substances with de minimis releases and exposures to qualify for the exemption. Are there alternative exemption criteria that would represent a reasonable proxy for de minimis exposure?

3. *Exemption notices.* To simplify the submission of low volume (LVE) and LoREX exemptions, and Agency review of them, EPA is proposing to require use of the PMN form (EPA Form 7710–25). Thus, submitters should supply the usual PMN information on chemical identity, impurities, trade names, production volume, uses, manufacturing sites, environmental release, and worker exposure. Given the importance of release and exposure information to the disposition of LVE and LoREX exemption notices, submitters should include as much information on these subjects as possible, including, where applicable, such items as an assessment of the potential for dermal and inhalation exposure, including magnitude, frequency, and duration; specific respirators used (e.g., NIOSH/MSHA-certified 19C Type C supplied-air respirator operated in pressure demand or positive pressure mode and equipped with a full face piece); specific information on the dermal protective equipment used (including any information on permeation); other control methods used (including information on their effectiveness); environmental release controls (including information on their efficiency); as well as details on work practices, standard operating procedures, etc. In assessing the potential for exposure, the submitter would be required to consider all routine worker activities during manufacture, processing, and use, including operations such as materials transfer, drumming, packaging or loading and associated unloading operations, sampling, etc. In assessing the potential for environmental release, the submitter would consider all routine releases during manufacture, processing, and use, including releases from processing, cleaning of equipment, disposal of empty containers, "off-spec" materials, processing waste, samples, etc.

Bald statements such as "glove boxes will be used" or "the chemical will be manufactured in a closed system" would be insufficient to document that worker exposure requirements of the LoREX exemption have been satisfied. For example, even manufacturing facilities controlling reactor operations via isolated control rooms may still involve potential worker exposures during such operations as sampling and drumming. Additional controls may be needed for these operations. Also, the efficiencies of such engineering controls as glove boxes or local exhaust ventilation (LEV) will vary according to manufacturer design, installation method, and user operations. Factors which may affect the operating efficiency of LEV include hood-to-source location, worker intervention, equipment installation, maintenance practices, and cross drafts. Because of such factors, actual efficiency may be lower than that claimed by the equipment manufacturer. Ventilation systems should be designed and operated in accordance with Occupational Safety and Health Administration (OSHA) standards such as 29 CFR 1910.94, and current recommendations of the manual Industrial Ventilation by the American Conference of Governmental Industrial Hygienists, and ANSI Z9.2 Fundamentals Governing the Design and Operation of Local Exhaust Systems published by the American National Standards Institute. The submitter would provide as much information as possible to demonstrate the effectiveness or efficiency of control methods, and procedures used to maintain the stated effectiveness of efficiency over time, as well as details on programs for worker safety training and hazard communication.

To the extent it is known or reasonably ascertainable by the submitter, physical and chemical property information for the chemical substance (e.g., vapor pressure, melting point, boiling point) would also be required under these proposed exemptions. This information would be listed on the last page of the PMN form. In EPA's experience, such information is generally available and would be helpful in assessing exposure controls and better characterizing the potential risk of the chemical substance.

The Agency believes use of the PMN form would prove beneficial to both it and industry, and seeks comments from experienced PMN and LVE submitters on this point. By providing a standard format for the required information, EPA expects to decrease the frequency with which it would have to conditionally deny incomplete exemption notices, thereby decreasing the length of time submitters would have to wait for disposition of their exemption notices and the Agency resources devoted to reviews.

Submissions not containing all of the required information would be declared incomplete. To reinitiate a notice which has been declared incomplete, a submitter would have to submit a complete new exemption notice form containing all the required information; partial submissions sent to EPA to supplement notices declared incomplete would not be accepted. Photocopied pages from previously submitted exemption forms would be accepted provided that the certifications page contains an original signature.

The proposal retains the provision which requires manufacturers of substances produced under the exemption to submit to EPA any test data or other information they obtain which indicates that the substance may not qualify for the exemption. The

proposal also adopts the current PMN requirement that requires submission of any new information of which the manufacturer obtains possession, control, or knowledge during the review period if that information materially adds to, changes, or otherwise makes significantly more complete the information included in the notice.

4. *EPA review of notices.* EPA is proposing, and requesting comment on, the requirement that submitters submit exemption notices 30 days prior to intended manufacture of the low volume or LoREX substance. The Agency believes that an increase from 21 days to 30 days will be necessary in order to accommodate the projected increase in number of exemption notices under the higher low volume ceiling and new LoREX category. EPA is aware a longer exemption review period may make the exemptions less attractive; however, it believes that the modest increase to 30 days proposed is imperative to conduct the type of reviews necessary to support the legal finding that the exempted substance will not present an unreasonable risk of injury to human health or the environment. Moreover, EPA believes that the existence of these two exemptions categories would, on average, significantly expedite the introduction of many new products into the marketplace.

5. *Determination that a chemical substance will be denied the exemption*— a. *During the review period.* Under this proposal, EPA would determine that a substance is ineligible for the low volume or LoREX exemptions if it finds that the new chemical substance does not meet the terms of the exemption, or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period. Such issues that may require further review include serious acute or chronic human health effects or significant environmental effects under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal.

If EPA determines during the review period that an exemption notice should be denied, the Agency will notify the manufacturer by telephone that the substance is denied the exemption. The submitter will subsequently be notified by letter. The letter will explain the reasons for EPA's determination. The submitter will then have the option of resubmitting the exemption notice with explanatory or additional information, submitting a PMN, or not manufacturing the chemical substance.

b. *After the review period expires.* The Agency is proposing to amend the current provisions relating to revocation of exemptions after expiration of the review period. Under the proposal, a revocation could be effected if EPA, based on new information, determines that it can no longer support the "no unreasonable risk" finding required under section 5(h)(4) of the Act. This is a change from the corresponding provision of the current exemption which permits revocations whenever EPA determines that the substance "does not meet the terms of this section."

6. *Inventory status.* For the expanded low volume exemption category for substances produced in quantities up to 10,000 kilograms/year, the Agency is proposing to continue the policy of not adding such substances to the TSCA section 8(a) Inventory of existing chemical substances. Similarly, EPA is proposing to not add substances produced under the LoREX exemption to the 8(a) Inventory. Therefore, subsequent manufacturers of chemical substances for which exemptions have been granted to other companies under these two categories will be required to submit independent exemption notices or PMNs before commencing nonexempted commercial production of those substances.

7. *Recordkeeping.* The proposed rule would require manufacturers and importers to maintain records on (a) the production volumes of the chemical substance for which an exemption was granted, and (b) documentation of information in the exemption notices and compliance with the terms of the exemption. The records would be maintained for 5 years after the date of their preparation. These records would be kept at the submitter's manufacturing site(s). Recordkeeping at the site of manufacture is a new requirement. The Agency has found that it has been difficult to determine compliance with the regulations when records are not kept at the site. Also under this proposal, EPA would have the authority to require the manufacturer of an exempt substance to submit copies of these records to EPA upon written request. Manufacturers would be required to provide these records within 15 days of the written notification by EPA. This section in the proposed rule is intended to supplement the inspection and subpoena authorities of section 11 of TSCA.

8. *User fees.* Section 26(b) of TSCA authorizes EPA to require, by rule, the payment of a reasonable fee from any person required to submit data under section 4 or 5 of TSCA. Currently, EPA requires a user fee for PMNs, certain PMN exemption notices, and significant new use notices submitted under TSCA section 5(a) and 5(h). EPA is proposing to amend 40 CFR part 700 to require manufacturers and importers to pay fees for low volume and LoREX exemption notices. Currently, there is no such user fee requirement associated with the low volume exemption. The proposed fee would be $100 for small business concerns, and $2,500 for all others.

The fee for PMNs, certain exemption notices, and SNURs was originally promulgated on August 17, 1988. The supporting rationale and background for this rule is published in the **Federal Register** of April 20, 1987 (52 FR 12940) and the **Federal Register** of August 17, 1988 (53 FR 31248). These two documents should be consulted for further information on the objectives and rationale for the user fee rule.

9. *Customer notification.* The Agency is proposing to retain the requirement that manufacturers notify processors and industrial users of the use restrictions and of any controls specified in the exemption notice. Such notification may be given by means of a container labeling system, written notification, or any other method that adequately informs recipients of the applicable use restrictions or controls. As with the existing LVE, the proposal also requires that manufacturers (a) immediately cease distribution to any customers who violate use or control restrictions, and (b) notify the Agency within 15 days of learning of such violations.

To ensure compliance with the LoREX criterion, the proposal requires further that LoREX exemption holders distribute LoREX substances only to persons who agree in writing to not further distribute the substances until they have been reacted or otherwise rendered into a physical form or state in which releases and exposures above the LoREX criterion will not occur. The Agency recognizes that this distribution restriction may be problematic for manufacturers of some substances used in multi-tiered markets, but believes that some form of control over distribution is necessary. Commenters are encouraged to suggest alternative methods EPA might employ to ensure that distribution of the LoREX substance beyond manufacturers' customers will not present an unreasonable risk to human health or the environment.

10. *Transfer of exemptions.* Current Agency policy generally does not recognize transfer of exemption rights between manufacturers; however, given the increased frequency over the last several years of corporate mergers,

acquisitions, buy-outs, technology transfers, and other forms of corporate succession, EPA believes that it is appropriate to reevaluate its exemption transfer policies in light of the proposed amendments and requests comments on this issue.

III. Rationale

A. Chemical Substances Manufactured at 10,000 Kilograms or Less Per Year

To better utilize its limited resources and lessen regulatory burdens on industry, the Agency undertook an examination of the review process for PMNs and PMN exemption notices to determine whether it was advisable to expand the categories of new chemical substances eligible for PMN exemptions. One of the first exemptions identified through this examination was the current exemption for new chemical substances manufactured in quantities of 1,000 kilograms or less per year. EPA believed that significant resource savings could be realized if the ceiling for the exemption could be raised to a level which would expand the pool of eligible new chemical substances while still permitting the Agency to make the requisite "will not present an unreasonable risk" statutory finding.

Those familiar with the PMN program will recall that in 1982 when the current low volume exemption ("LVE") was originally proposed (47 FR 33920), the Agency included a separate category for chemical substances manufactured in quantities of 10,000 kilograms or less per year. However, that portion of the proposal was never promulgated. This was due mainly to uncertainty over the number and types of notices that would be received under the higher volume category, and also to an inability to reconcile industry concerns over some of the additional safeguards imposed upon the higher volume category and the Agency's belief that such safeguards were necessary (see the discussion in Unit I. of this preamble).

With the benefit of 8 years of experience under the 1,000 kilogram exemption category and the Agency's enhanced ability to gauge toxicity of new chemical substances based upon structural activity relationships, EPA is confident that it can now review a larger pool of chemical substances under the low volume exemption and identify within an abbreviated review period those substances which may pose an unreasonable risk to human health or the environment.

The basic rationale for proposing an expansion of the low volume exemption category is the same as that for proposing the exemption initially: chemical substances produced in lower quantities generally involve correspondingly lower human exposures and environmental releases, and consequently, present generally less risk than high volume substances. Beyond this, the Agency believes that the low volume exemption has been a very successful regulatory mechanism as measured by the level of EPA administrative resources needed to implement it and the relative burden it places on manufacturers. Because of this success, EPA believes that both its interests and the interests of industry and the public will be served by enlarging the portion of new chemical substances which may be manufactured under the exemption.

B. Low Release and Exposure (LoREX) Chemical Substances

In addition to the production volume-based category described above, EPA is proposing establishment of a new TSCA section 5(h)(4) exemption category based on low levels of environmental release of, and human exposure to the new chemical substance. Eligibility would be independent of production volume level.

The Agency believes that the concept of basing an exemption on low release and exposure offers several potential advantages over a volume-based exemption. First, an exposure-driven exemption generally provides a more direct gauge on the magnitude of risk presented by a given new chemical substance. Production volume alone is only an indirect indicator of exposures and releases. Secondly, EPA believes that the existence of a LoREX exemption will encourage pollution prevention (source reduction) techniques by rewarding manufacturers able to meet the low release and exposure criteria with more timely regulatory decisions, and in many cases, with less burdensome regulatory controls. Such a result would entail substantial time and resource savings for both EPA and industry.

1. *LoREX criteria* — a. *Human exposure.* In determining the appropriate criteria for defining the types and/or levels of exposure which should constitute "low exposure" to humans, EPA considered three distinct populations: workers, consumers, and the general population. EPA believes that, for purposes of this exposure-based exemption, any direct exposures to the latter two groups would be, in the context of an abbreviated review period, inconsistent with the Agency's statutory obligation under section 5(h)(4) to affirmatively find that the exempted substances will not present an unreasonable risk to human health. Therefore, the Agency believes that any consumer and/or general population exposures (other than the negligible drinking water and ambient air exposures discussed later in this preamble) should automatically disqualify new chemical substances from LoREX exemption eligibility.

Exposures to workers, on the other hand, are fundamentally different than consumer and general population exposures in that they may be more readily monitored and controlled through engineering controls, workplace practices, and/or protective equipment requirements. Therefore, the Agency believes that it may, consistent with its section 5(h)(4) obligation, approve a high percentage of LoREX exemption notices where appropriate control measures are instituted in the workplace.

Workplace exposures may occur through inhalation, dermal contact, or ingestion. For dermal/ingestion exposures, the Agency believes it most appropriate to require manufacturers applying for a LoREX exemption to comply with the general dermal exposure requirements used in section 5(e) consent orders; namely, to require all workers reasonably likely to be exposed to LoREX substances to be provided with, and required to wear, chemical protective equipment which provides a barrier to prevent all dermal exposure to the substance. Chemical protective clothing used to provide this barrier must be demonstrated to be impervious to the substance under the expected conditions of use and duration of exposure. Such demonstration could be accomplished under 40 CFR 721.63(a)(3)(i)-(ii) by actually testing the material used to make the chemical protective clothing and/or by evaluating the specifications from the manufacturer or supplier of the chemical protective clothing to establish that the chemical protective clothing will be impervious to the exempted substance alone and in likely combination with other chemical substances in the work area.

Regarding inhalation exposure, the Agency will expect submitters for LoREX exemption notices to have (i) identified the workplace operations where inhalation exposure is likely to occur; (2) assessed the magnitude, frequency, and duration of potential exposure; (3) assessed the effectiveness of the various exposure controls; and (4) selected the method or combination of methods that will provide workers with the appropriate protection for the given workplace. While the Agency strongly encourages submitters to reduce workplace exposures at their source,

where feasible, submitters could also support a claim of low worker inhalation exposure based on the use of appropriate respiratory protection equipment. The Agency believes it most appropriate for a submitter to comply with the general requirements regarding respiratory protection used in TSCA section 5(e) consent orders, which stipulate the use of respiratory protection in accordance with the National Institute of Occupational Safety and Health (NIOSH) regulations at 30 CFR part 11, and the Occupational Safety and Health Administration (OSHA) regulations at 29 CFR 1910.134. Similarly, the inherent physical or chemical properties of the substance submitted for an exemption may form the basis of a low exposure claim, as in a nonvolatile dye manufactured, processed, and used only in solution, such that inhalation to particulates will not occur.

b. *Environmental release*— i. *Water releases.* The proposed LoREX water release eligibility criterion of <1 ppb surface water concentration was established on the basis of EPA's experience in conducting environmental risk assessments on PMN substances. The concentration level is to be estimated by the submitter using the method described in 40 CFR 721.90. Based on EPA's 14 years of PMN experience, aquatic toxicity concern levels have only very rarely been established at levels below 1 ppb. Thus, EPA is confident that the vast majority of LoREX exemption notices satisfying this criterion will not present an unreasonable risk of acute or chronic aquatic toxicity, and that the Agency's risk assessment capabilities will identify those few exemptions which may require more strict concentration levels to protect against potential aquatic risks.

ii. *Air releases.* The proposed LoREX air release eligibility criterion of 1 $\mu g/m^3$ was, like the ambient surface water criterion, selected on the basis of experience gained in conducting risk assessments on over 18,000 PMN chemical substances since 1978. At this maximum annual average concentration, EPA believes that, using worst case estimates, the maximum human exposures downwind from incinerators will be toxicologically insignificant for most of the chemical substances it is likely to review under the LoREX exemption. As noted above, however, the Agency may require individual submitters to adhere to lower release levels for substances for which chronic toxicity concerns are raised during the risk assessment.

The proposed methodology for calculating maximum annual average concentration (see Table 1, footnote 5) to be used by exemption notice submitters was based on computer modeling similar to that used by the Agency in the PMN review process. Those interested in more detail on this methodology should consult the docket.

Submitters should also be aware that, although the proposal has not established generic eligibility criteria for fugitive air emissions unrelated to incineration, the Agency will review the potential for such emissions on a case-by-case basis, and will deny exemptions if the air emissions reach such levels as to undermine the Agency's ability to conclude that the substances in question will not present an unreasonable risk.

iii. *Land/groundwater releases.* The Agency is proposing to exclude from eligibility all chemical substances which will be disposed of via landfill unless the submitter demonstrates that the exempted substance has negligible ground-water migration potential. This "zero release" standard was deemed most appropriate because the Agency was unable to develop a broadly applicable method for estimating groundwater concentrations of chemical substances based on landfill disposal volume. Given the many variables involved in making such estimates (e.g., migration rates, biodegradation rates, sediment/soil adsorption rates), EPA does not believe it will be possible to develop a generic model for estimating groundwater concentrations for a significant number of substances with sufficient reliability to support the requisite "no unreasonable risk" finding. Consequently, the Agency believes that, in the context of an abbreviated review period, where in-depth case-by-case assessments of groundwater leaching potential are infeasible, prudence dictates that zero release be the primary standard.

Potential LoREX exemption submitters with no viable alternatives to landfill disposal would be given the option under the proposal of demonstrating to the Agency's satisfaction that their substance will not migrate to groundwater. A list of suggested tests to establish groundwater migration potential is contained in Unit II.A.2. of this preamble. If such a demonstration is made, a submitter would be permitted to landfill excess quantities of the exemption substance up to the amounts approved in its exemption. In all cases, however, the Agency strongly encourages submitters to strive for total elimination of releases through employment of the best available pollution prevention (source reduction) techniques.

IV. Major Alternatives Considered

A. Maximum Annual Production Limit

As an alternative to the 10,000 kilogram annual production limit proposed in this notice, the Agency considered raising the low volume production ceiling to either (1) 5,000 kilograms; or (2) 25,000 kilograms with a toxicity testing requirement.

Based on PMN data, EPA estimated that a 5,000 kilogram ceiling would increase the pool of chemical substanc eligible from the current 1,000 kilogra exemption by 10 percent, or 21 percen of all PMN submissions. Although this increase is not insignificant, the Agenc believes that it would not utilize this exemption to the extent possible, and that a higher volume ceiling, benefitin both EPA, the public, and industry, could be proposed consistent with the Agency's statutory mandate to make th "no unreasonable risk" finding; thus, EPA favored the 10,000 kilogram alternative over the 5,000 kilogram alternative.

The 25,000 kilogram option, with a "minimum toxicity data set" requirement, was also considered by t Agency during development of the proposed rule. This higher volume ceiling was projected to encompass approximately 38 percent of all new chemical submissions, a 27 percent increase over the number of submissions under the current exemption. Although EPA believes th increasing the maximum volume to th level could potentially save both it an industry considerable time and resources for a large number of new chemical substances, this option raise a number of concerns. Chief among those concerns was the cost of testing. If the Agency were to require LVE submitters to conduct the same "core set" of health and ecotoxicity testing i now requires of submitters of high volume/high exposure PMN substanc under its "exposure-based" criteria pursuant to section 5(e)(1)(A)(ii)(II) of TSCA, the average per chemical cost of such testing would be over $50,000. Even if such a data development requirement were delayed until a specified volume of the chemical substance was produced, there is considerable uncertainty over how many potential submitters would find that form of an exemption preferable a PMN submission. On the other hand if EPA were to scale back the data development requirements, there is doubt that the Agency could make th requisite "no unreasonable risk" find for many of the submissions. Consequently, in light of these uncertainties, EPA determined that it

would be inadvisable at this time to propose a new low volume category for substances produced in the 10,000 to 25,000 kilogram range.

B. Site-limited Intermediates

The Agency originally proposed a site-limited intermediate (SLI) exemption category in 1982 but, as with the proposed 10,000 kilogram low volume category, never promulgated a rule for that category due to industry criticism of the proposed procedural safeguards and EPA's uncertainties over making the "no unreasonable risk" finding for this class of substances without such safeguards. EPA considered reproposing the SLI exemption category in this rulemaking, but decided against doing so mainly because it believes that most, if not all, SLI chemicals which would be approved under an SLI exemption would fall within the scope of the LoREX exemption category; therefore, the Agency believes that a separate SLI exemption is unnecessary. Nevertheless, EPA is outlining the parameters of an SLI exemption alternative in this section to solicit public comment on this concept.

If proposed as a separate exemption category, the SLI exemption would be available to all domestic manufacturers of chemical substances satisfying the definition of "site-limited intermediates", independent of annual production volume. Under the 1982 proposal, an "intermediate" was defined as "any chemical substance which is (1) used as a reactant in the intentional manufacture of another chemical substance, and (2) is consumed in whole or in part in that reaction"; and a "site-limited intermediate" was defined as an "isolated intermediate which is manufactured, processed, and used only at the site of manufacture and not intentionally distributed outside that site except as waste which will be delivered for disposal in accordance with applicable government laws and regulations, or for burning as a fuel".

As with the low volume and LoREX exemption categories, the Agency would conduct a risk assessment of the SLI based upon the information submitted by the manufacturer, and would approve the exemption only upon a finding that the substance would not present an unreasonable risk to human health or the environment. Certain hazard or exposure concerns identified during the 30–day review period would be grounds for a denial of the exemption notice. For example, significant human exposures or releases that could not be adequately mitigated through controls or waste treatment would prevent the Agency from making the requisite "will not present an unreasonable risk" finding.

The Agency believes, as it did in 1982, that site-limited intermediates as a class may be considered low risk because they are largely consumed in chemical reactions and thus do not generally leave the site of manufacture, either in emissions, waste or final products, except in relatively small amounts. Moreover, to the extent that workers may be exposed to SLIs at manufacturing sites prior to initiation of the chemical reaction, such exposures can typically be adequately controlled through employment of protective equipment, engineering controls, and/or workplace practices. However, as stated above, the Agency is not convinced at this time of the need for both an SLI exemption category and a LoREX exemption category. Therefore, The Agency will consider promulgating a separate exemption category for SLIs in the final rule only if either (1) the LoREX category is substantially altered in the final rule, or (2) public comment convinces EPA that there could be a significant number of low risk SLIs which would not satisfy the LoREX eligibility criteria.

V. Alternatives and Request for Public Comment

EPA requests comments and data on all aspects of this proposal, including provisions of § 732.50 that EPA has proposed to retain unchanged from the 1985 exemption. EPA will consider all comments and data received during the comment period and may amend any provision of § 723.50 where appropriate, based on these comments.

VI. Regulatory Analysis

A. Summary of Risk Assessment

1. *10,000 kilogram/year chemical substances.* To assess the risk associated with raising the ceiling for chemical substances eligible for the low volume exemption from 1,000 kilograms/year to 10,000 kilograms/year, the Agency relied primarily upon the risk assessment developed to support the 1985 final low volume rule, along with the earlier version used to support the 1982 proposed low volume and site-limited intermediate rules.

a. *Exposure assessment.* The exposure assessment illustrates that, while low production volume in itself limits potential for exposure and environmental release, manufacture, processing, and use of such chemicals can in some circumstances result in significant exposures at both the 1,000 and 10,000 kilogram annual production levels.

i. *Occupational exposure.* Based on PMN data, the number of workers exposed during manufacturing ranged from an average of about four for chemical substances manufactured in quantities of 1,000 kilograms or less per year to an average of about eight for chemical substances manufactured in quantities of 10,000 kilograms or less per year. Duration of exposure associated with manufacture averaged about 5 hours per day at both production levels, and the average number of days of production per year was 62.

Only a limited number of PMNs included estimates of workplace concentration. The average concentrations associated with manufacture were most often in the ranges of 0 to 1 and 1 to 10 mg/m^3 for airborne solids and in the 1 to 10 ppm range for vapors. EPA's evaluation of OSHA data (USEPA, OTS "Site-Limited Intermediate Exemption: Occupational Exposure and Environmental Release Assessment." March 19, 1982) indicated a time weighted average (TWA) of 6 ppm, with a maximum value of 72 ppm for vapors. EPA believes that data obtained from OSHA monitoring activities provide more reliable estimates of workplace concentrations.

EPA's analysis of processing and use of low volume chemicals indicated that the wide variety of possible processing and use operations can result in a wider range and higher level of exposures than typically associated with manufacturing operations. The average number of workers exposed during processing and use operations exceeded the average numbers typically exposed during manufacturing. The number ranged from an average of 12 workers for a chemical processed in quantities of 1,000 kilograms or less per year to an average of 141 workers for chemicals processed or used in quantities of 10,000 kilograms or less per year.

ii. *Consumer exposure.* Consumer exposures were assessed for five use scenarios: photographic chemicals used in home darkrooms; spray adhesives; paints; dyes; and fragrances used in soaps and detergents. The use scenarios, which reflected actual uses reported in PMNs, were selected to represent divergent and potentially significant exposure situations. In these scenarios, the individual lifetime average daily exposures were estimated to range from 0.0016 mg/kg/day for a fragrance in soap to negligible levels for dyed fabrics.

According to EPA's analysis, many of the consumer use scenarios could result in relatively large numbers of

consumers exposed. The numbers of consumers potentially exposed at the 10,000 kilogram production level ranged from 76,000,000 for a fragrance in shampoo to 98,000 for a spray adhesive. Because the concentration of a new chemical substance in a final product remains constant, the production volume is likely to affect only the number of consumers exposed, not the exposure level to each individual. Therefore, the number of consumers exposed at the 10,000 kilogram production limit is about 10 times the number that would be exposed at the 1,000 kilogram limit.

b. *Environmental release.* Environmental release from manufacturing and the resultant environmental concentrations were estimated for low volume chemicals. EPA relied on PMN data in estimating the duration and frequency of releases. However, PMN projections of the amount released were considered less reliable than other sources of information.

The exposure analysis indicated that the average quantity released to water is 0.08 percent of the production volume, with an upper bound of 0.4 percent. Amounts released to air average 0.03 percent of production volume, with a 0.2 percent upper bound. However, some processing and industrial uses result in more substantial release rates, with a range from 0.3 to 25 percent of the production volume released to water. Discharges of a new low volume chemical from a single site processing 10,000 kilograms of the chemical were estimated to produce environmental concentrations ranging from less than 0.0005 to 5.2 ppm in a receiving stream whose stream dilution factor was equal the national median for streams receiving effluent from industrial facilities.

In some cases, such as detergent additives, environmental release from consumer uses equaled the total production volume; however, the actual magnitude of environmental exposure was determined to be insignificant due to the low production volume, the wide distribution of release, and the small amount of new chemical typically contained in each consumer product.

c. *Risk under exemption conditions.* There are several elements of the proposed exemption amendment that would significantly reduce risks to human health and the environment.

Chemical substances with carcinogenic, teratogenic, neurotoxic, and other chronic effects appear to present the greatest risks even at relatively low exposures. The proposed provisions which permit the Agency to deny exemptions for substances which may present unreasonable risks for those effects should significantly reduce the likelihood that chemicals that present such risks would be manufactured under the amended exemption. If the exemptions for such chemicals are denied, or if their submitters are required to resubmit their exemption notices to provide for more stringent release and exposure controls, the range of potential risks would be substantially below the high end of EPA's estimates.

In addition, under the proposed amendments, EPA would continue to review all exemption notices during the 30–day review period. This review will help ensure that manufacturers choose appropriate safeguards to control risks, as well as provide a screen to identify chemicals that do not qualify for the exemption.

2. *Low release and exposure chemical substances.* The risk associated with a given substance is a function of both the inherent toxicity of the substance and the exposure of the relevant organism to the substance. Therefore, to the extent that releases and exposures are maintained below certain critical levels, potential risks presented by the substance are minimal. In order to assess the potential risk associated with the proposed LoREX exemption, the Agency evaluated the proposed exposure and release criteria in the context of its experience conducting risk assessments on over 13,000 new chemical substances in the PMN program over the last 12 years. Based on this experience, EPA tailored its LoREX exemption criteria in a manner to exclude from eligibility the large majority of chemical substances which may present significant human or environmental risks under conditions of manufacturing, processing, and use. For those substances which meet the eligibility criteria but may nevertheless present significant risks due to unusually high predicted toxicity levels, the Agency will either deny the exemptions or condition approval upon satisfaction of stricter exposure and release requirements.

a. *Human exposure.* Due to the wide range of potential consumer and general population exposures which are possible from the universe of new chemical products, the Agency concluded that it could not develop any meaningful consumer or general population exposure criteria which would consistently screen out those substances which would present significant risks from direct dermal or inhalation exposures. Consequently, EPA has proposed to exclude from LoREX exemption eligibility all new chemical substances which entail any direct consumer or general population exposure (except for negligible drinking water and ambient air exposures discussed in Unit A.2.b. of this preamble) New chemical substances intended for use in paints, soaps, dyes, and other consumer products, therefore, would have to be reviewed by the Agency in a full PMN notice or under one of the other applicable PMN exemptions.

Under the proposed LoREX criteria applicable to workers, only those chemical substances with no dermal exposures and no unprotected inhalation exposures to workers will be eligible to apply for the exemption. Therefore, to the extent that pollution prevention practices, the required methods of control, engineering controls, protective equipment, work practices, etc., will maintain inhalation and dermal exposure below critical levels, potential risks presented by the exempted chemical substances will be minimal.

b. *Environmental release.* In terms of environmental releases, LoREX eligibility criteria for releases to three environmental media are proposed. For ambient surface water, the Agency is proposing that submitters either (i) prevent all direct and indirect releases of the exempted substance to surface waters; or (ii) demonstrate that any releases to water that may occur will result in surface water concentrations of the substance that are no greater than 1 part per billion (ppb) using the surface water concentration calculation method described in 40 CFR 721.90. Based on Agency worst case assumptions for drinking water exposure estimates, surface water concentrations of 1 ppb will result in human drinking water exposures at or below the 1 mg/year LoREX drinking water criterion in nearly every case; therefore, compliance with the drinking water exposure criterion will be presumed from compliance with the 1 ppb surface water level. The Agency will reserve the right, however, to require lower surface water concentrations on a case-by-case basis when concerns for carcinogenicity, neurotoxicity, or other effects are raised, or under conditions where actual drinking water exposures are likely to significantly exceed the 1 mg/yr dosage.

The LoREX eligibility criterion for maximum annual average ambient air release concentration from incineration is 1 $\mu g/m^3$. This level was derived from air exposure modeling estimates of maximum ground level concentrations from incinerator stacks, using worst case meteorological data sets. To determine

whether a particular substance meets the criteria, submitters would calculate exposure levels using the method described in Table 1. As with drinking water exposures, the Agency may require lower air release levels in individual cases if concerns for chronic health effects are raised for the exempted substance.

For land/groundwater disposal, EPA is proposing that a LoREX substance not be disposed of by landfill or other land disposal methods unless the submitter demonstrates that the substance will not migrate to groundwater. To make such a demonstration, a submitter would be required to provide data on the biodegradation and leaching potential of the exempted substance, or other data that clearly establish that releases to groundwater will not occur. EPA suggests the following core set of tests to establish groundwater migration potential: (1) An inherent biodegradability in soil test (40 CFR 796.3400); (2) an anaerobic biodegradability of organic chemicals test (40 CFR 796.3140); and (3) depending on the substance's chemical properties, either a sediment and soil adsorption isotherm test (40 CFR 796.2750) or a soil adsorption isotherm test (40 CFR 796.2700). EPA strongly suggests that submitters contact the EPA Prenotice Coordinator (telephone: (202) 260–1745) for guidance prior to commencement of the above testing.

Upon approval of a LoREX exemption, the submitter would be bound to the continuous use of the exposure and release controls described in the approved exemption notice, as well as the listed uses and manufacturing sites. The Agency would deny an exemption notice notwithstanding satisfaction of the exposure-based exemption criteria if it believes it cannot support the affirmative finding required under section 5(h)(4) of TSCA that the manufacture, processing, distribution, use, and disposal of the chemical substance, under the conditions described in the notice, will not present an unreasonable risk to human health or the environment.

VII. Economic Impact

The regulatory impact analysis estimates the costs and benefits attributable to the proposed regulation. In this case, the analysis also contains estimates for the three additional proposed amendments to Section 5 regulations, namely the Polymer Amendment, the Procedural Amendment, and the Non-5(e) Significant New Use Rule Amendment. Because these proposed regulations are amendments to current regulations, the costs and benefits are incremental, estimating the effect of the proposal with respect to the current regulation.

The costs and benefits associated with this proposed amendment are partially quantified; many of the benefits are unquantified but are expected to be of significant importance. Considering only the quantified costs and benefits, there is a cost savings in most instances. Assuming either 1,000, 2,000, or 3,000 annual Section 5 submissions, the savings as compared to the current regulation are estimated to be:

Annual Number of Submissions	Annual Cost Savings ($ Million)	
	Industry	Government
1,000	(0.2)–0.4	1.3–1.5
2,000	(0.4)–0.7	2.5–3.1
3,000	(0.5)–1.0	3.8–4.8

This proposed amendment affects the low volume exemption and establishes a low release/low exposure exemption (LoREX). Industry costs associated with the proposed amendment to the low volume exemption are reporting costs, delay costs, and a user fee. Per submission reporting costs are increased due to the more comprehensive submission requirements. Delay costs for those substances which qualify for the current exemption are slightly higher, while delay costs are significantly reduced for those substances which currently must submit a full PMN submission but would qualify for the proposed exemption. Delay costs are the costs associated with the delayed introduction of the substance into the market due to Section 5 regulations. In addition, a user fee has been added to the amendment.

Industry costs associated with the proposed LoREX exemption are also reporting costs, delay costs, and a user fee. Because this would be a new exemption, all of the submitters would have originally been required to submit a full PMN submission and would already be required to pay a user fee. Also, the reporting requirements are only slightly more than current requirements.

Unquantified benefits associated with this proposed amendment include increased voluntary use of pollution prevention practices by submitters and a greater emphasis on the use of low risk chemicals.

The Agency's complete economic analysis is available in the public record for this rule (OPTS–50596).

VIII. Finding of No Unreasonable Risk

1. *Statutory background.* Under section 5(h)(4) of TSCA, EPA is authorized to exempt the manufacturer of any new chemical substance from all or part of the requirements of section 5 if EPA determines that the manufacture, processing, distribution in commerce, use, and disposal of the substance will not present an unreasonable risk of injury to human health or the environment. Section 26(c) of TSCA provides that any action authorized under TSCA for an individual chemical substance may be taken for a category of such substances. Under this proposal, EPA will be exempting chemical substances with production volumes less than or equal to 10,000 kilograms/year and chemical substances with low human exposure and low release to the environment. For each of these categories, as discussed below, EPA has made a finding that, as a general matter, chemical substances eligible for the exemptions will not present an unreasonable risk of injury when manufactured, processed, used, distributed in commerce, or disposed of under the terms of the proposed exemptions.

The term "unreasonable risk" is not defined in TSCA. The legislative history, however, indicates that unreasonable risk involves the balancing of the probability that harm will occur and the magnitude and severity of that harm against the effect of the proposed regulatory action on the availability to society of the benefits of the chemical substance.

2. *Risks.* In making the "no unreasonable risk" finding under TSCA section 5(h)(4), EPA first considered the risk posed by granting each of the exemptions. Risk is the combination of the hazard presented by a chemical substance and the exposure of humans or the environment to the substances. EPA's determination of the reasonableness of risk involves a consideration of factors such as environmental effects, distribution, and fate of the chemical substance in the environment, disposal methods, waste water treatment, use of protective equipment and engineering controls, use patterns, and market potential of the chemical substance. These variables are difficult to quantify and standardize, thereby requiring EPA to supplement available data with its professional judgment.

EPA's preliminary determination of no unreasonable risk is based on consideration of (i) the limitations on risk that would result from the safeguards built into the rule, including

Agency review; (ii) the limitations on risk resulting from the restriction of exemptions to chemical substances manufactured at volumes of 10,000 kg/yr or less and to low exposure/low release chemical substances; (iii) the benefits to industry and the public provided by chemical substances manufactured under the exemption; and (iv) the benefits to the public and the Agency from the Agency's enhanced ability to utilize its limited resources on reviewing chemical substances and uses of high risk and concern. EPA recognizes that, even with the safeguards imposed by this rule, the proposed approach would not ensure that there would be no risk from chemicals manufactured under the exemption. The statute does not define no unreasonable risk to be zero risk. Rather, it defines no unreasonable risk as a balancing of risk and benefit. Because of the safeguards in the proposed rule, the requirement that the provisions of the approved exemption are binding on the submitter, and the restricted nature of the exemption categories, EPA believes that risks are not likely to be any greater than if the full PMN process were completed. Furthermore, the new chemical substances provide benefits to industry and to the public. These benefits are an important element in the finding of no unreasonable risk.

The proposed conditions of these exemptions are designed to mitigate risk, largely by the use of: (i) the reviews conducted by the Agency to assess whether the new chemical substances may cause chronic or acute human health or environmental effects; and (ii) the binding nature of the provisions of exemption notices, including the controls placed on exposure through worker protection requirements. For the LVE, EPA determined that risks would generally be low because low production volume chemicals typically are not expected to result in high exposure to humans or the environment. Similarly, the eligibility criteria for the LoREX exemption directly limit permissible releases of and exposures to the exempted substance. In addition to the general finding of low release/exposure, and therefore low risk for these categories, the restrictions and safeguards built into the proposed exemptions will ensure that the risks presented by the exempt substances are low. For example, worker protection requirements and release restrictions imposed through the terms of the exemptions will minimize exposure, and therefore, risk.

a. *EPA review.* Within the 30-day review period, EPA is confident that it can identify chemical substances posing potential risks requiring more detailed and comprehensive review. EPA's abbreviated review plays an important role in the exemptions and in the finding of no unreasonable risk. EPA is proposing to lengthen the review period from 21 to 30 days to ensure that staff resources will be sufficient to review the increased number of exemption notices expected under the amended rule and the increased amount of information required of each notice. Information submitted will include production volume, hazard information, descriptions of the manufacturing, processing, and uses, releases to the environment, and certain physical/chemical data which EPA will assess in making a determination of risk. During this period, the Agency will have sufficient time to identify any problems that were likely to have been identified in a full PMN review. If EPA determines that a new chemical substance is not eligible for an exemption, manufacture could not begin. The manufacturer would then be required to comply with TSCA section 5(a)(1) before the substance could be manufactured for commercial purposes by submitting a full PMN to the Agency.

b. *New information and EPA revocation.* In addition to these safeguards, the proposed rule contains several other provisions that will further limit the possibility that exempted substances will present significant risks. Most important, the proposed rule establishes procedures for revocation of the exemption if EPA later determines that the substance may present an unreasonable risk. In addition, EPA would have the authority to require documents relevant to an exemption from the manufacturer (in addition to the information provided in the exemption notice), and the manufacturer would be required to submit promptly to EPA any new data indicating that a substance is ineligible. These provisions will ensure that eligibility for and continuation of the exemption will be determined on the basis of the best available information, regardless of when the information becomes available.

3. *Benefits.* EPA believes that these proposed exemptions will allow many manufacturers to introduce new chemical substances in commerce much more rapidly than via the PMN process. The time and resource savings will also benefit EPA which will, by utilizing its limited assets more efficiently, be able to apply more staff time to reviewing higher risk chemical substances and uses.

4. *Pollution prevention considerations.* The proposed LoREX exemption is expected to further the Agency's pollution prevention efforts by encouraging development of manufacturing processes and technologies which reduce chemical releases and exposures at their source. Such reductions not only limit potential risks to people and the environment, but also many times produce significant long-term cost savings to industry through the recapture and reuse of substances which would otherwise have been released into workplaces or the environment.

5. *Risk/benefit balance.* As discussed above, EPA has determined that the risk presented by exempting these chemical substances is low. At the same time, there are significant benefits to be achieved by the exemptions, which encourage innovation and permit manufacturers to introduce new chemicals into commerce more rapidly. Thus, EPA has determined that, as a general matter, the risks associated with low volume substances and low release/low exposure substances are outweighed by the benefits to society of exempting these substances from full PMN review.

6. *Exclusion.* Despite the low risk generally associated with low volume and low release/low exposure substances, EPA recognizes that for some substances that may meet the general requirement for these exemptions, it may not be possible to make a finding of no unreasonable risk. For example, a highly toxic chemical may present an unreasonable risk even if exposure to the chemical is low. Likewise, a low production volume chemical may present an unreasonable risk if it is hazardous and is manufactured or processed in a manner that would result in high human exposure or high release to the environment. Thus, although EPA is making a general "no unreasonable risk" finding for categories of chemical substances, EPA will continue to evaluate exemption notices on a case-by-case basis to determine if individual substances should be excluded from the general exemption categories based on the potential risks presented by those substances. For a further discussion of how EPA will determine when to exclude an individual substance from the general exemptions see Unit III. of this proposal.

IX. Rulemaking Record

Interested persons may submit written comments regarding this proposal to the TSCA Document Control Officer (TS-790), Office of Prevention, Pesticides,

and Toxics, 401 M St., SW., Washington, DC 20460. Commenters representing corporations or trade associations must submit three copies of all comments; individuals may submit single copies of comments. The comments must be identified with the document control number "[OPTS–50596]".

EPA has established a record for this rulemaking (docket control number OPTS–50596). The record includes basic information considered by the Agency in developing this proposed rule. A public version of the record without any confidential information is available in the TSCA Public Docket Office from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE–G004, 401 M St., SW., Washington, DC.

K. Other Regulatory Requirements

A. Executive Order 12991

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition, costs, or prices.

This proposed regulation was submitted to the Office of management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the notice submitters were small firms, since the rule would generally reduce the burden and cost of all PMN requirements for such businesses.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et. seq. and have been assigned OMB control number 2070–0012.

The public reporting burden for this collection of information is estimated to vary from 96 to 116 hours per response, with an average of 106 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Parts 700 and 723

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Reporting and recordkeeping requirements.

Dated: January 19, 1993.

William K. Reilly,
Administrator.

Therefore, 40 CFR chapter I, is proposed to be amended as follows:

PART 700 — [AMENDED]

1. In part 700:

a. The authority citation for part 700 continues to read as follows:

Authority: 15 U.S.C. 2625.

a. In § 700.43 by revising the definition of "Exemption notice" to read as follows:

§ 700.43 Definitions.

* * * * *

Exemption notice means any notice submitted to EPA under § § 723.50 or 723.175 of this chapter.

* * * * *

b. In § 700.45 by revising paragraph (c) and the parenthetical text at the end of § 700.45 to read as follows:

§ 700.45 Fee payments.

* * * * *

(c) Persons are exempt from remitting any fee for submissions under § 720.38 of this chapter.

* * * * *

(Approved by the Office of Management and Budget under control number 2070–0012).

PART 723 — [AMENDED]

2. In part 723:

a. The authority citation for part 723 would continue to read as follows:

Authority: 15 U.S.C. 2604.

b. By revising § 723.50 to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and certain chemical substances with low environmental releases and human exposures.

(a) *Purpose and scope.* (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of (i) certain chemical substances manufactured in quantities of 10,000 kilograms or less per year, and (ii) certain chemical substances with low environmental releases and human exposures.

(2) To manufacture a new chemical substance under the terms of this exemption a manufacturer must:

(i) Submit a notice of intent to manufacture 30 days before manufacture begins, as required under paragraph (e) of this section.

(ii) Comply with all other provisions of this section.

(b) *Definitions.* The following definitions apply to this subpart.

Act means the Toxic Substances Control Act (15 U.S.C. 2601 et seq).

Category of chemical substances has the same meaning as in section 26(c)(2) of the Act (15 U.S.C. 2625(c)(2)).

Environment has the same meaning as in section 3 of the Act (15 U.S.C. 2602).

Environmental transformation product means any chemical substance resulting from the action of environmental processes on a parent compound that changes the molecular identity of the parent compound.

Metabolite means a chemical entity produced by one or more enzymatic or nonenzymatic reactions as a result of exposure of an organism to a chemical substance.

Serious acute effects means human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

Serious chronic effects means human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or

prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

Significant environmental effects means:

(1) Any irreversible damage to biological, commercial, or agricultural resources of importance to society;

(2) Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or

(3) Any known or reasonably anticipated loss of members of an endangered or threatened species. Endangered or threatened species are those species identified as such by the Secretary of the Interior in accordance with the Endangered Species Act, as amended (16 U.S.C. 1531).

The terms *byproduct, EPA, importer, impurity, known to or reasonably ascertainable, manufacture, new chemical substance, person, and test data* have the same meanings as in § 720.3 of this chapter.

(c) *Exemption categories.* This exemption applies to (1) manufacturers of each new chemical substance manufactured in quantities of 10,000 kilograms or less per year under the terms of this exemption, and (2) any manufacturer of a new chemical substance satisfying all of the low environmental releases and human exposure eligibility criterion in the following Table 1:

TABLE 1.—PROPOSED LOW RELEASE/EXPOSURE (LOREX) ELIGIBILITY CRITERIA[1]

Type of Exposure or Release	Eligibility Criteria for Exemption
Human Exposure	
General Population Exposure.	
Dermal:	None
Inhalation:	None[2]
Drinking Water:	<1 mg/yr[3]
Consumer Exposure.	
Dermal:	None
Inhalation:	None
Worker Exposure.	
Dermal:	None
Inhalation:	None, unless adequate protection provided
Environmental Release	
Ambient Surface Water Releases.	No releases resulting in surface water concentrations above 1 ppb[4]
Ambient Air Releases	No incineration releases above 1 µg/m³ maximum annual average concentration[5]
Land/Groundwater Releases.	No releases to landfill unless submitter demonstrates that the exempted substance has negligible ground-water migration potential

[1] This table lists the minimum criteria required to apply for the exemption. Based on the review of the notice, lower concentrations may be required by the Agency for substances with potential for carcinogenic, neurotoxic, or other effects.
[2] No inhalation exposure permitted except as provided under the ambient air incineration criteria.
[3] Estimated average dosage resulting from drinking water exposures in streams with maximum allowable concentration permitted under ambient surface water criteria (1 ppm).
[4] Concentration to be calculated using methods prescribed in 40 CFR 721.90.
[5] Using following formula: (kg/day release after treatment) X (release days/year) X 9.68 X 10^6 µg/m³.

Manufacturers of chemical substances that qualify for an exemption under both paragraph (c)(1) and (c)(2) of this section may apply for either exemption, but not both.

(d) *Chemical substances that cannot be manufactured under this exemption.* A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraphs (c)(1) or (c)(2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or any reasonably anticipated impurities in the substance may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance—

(1) Serious acute (lethal or sublethal) effects.

(2) Serious chronic (including carcinogenic and teratogenic) effects.

(3) Significant environmental effects.

(e) *Exemption notice.* (1) The manufacturer must submit an exemption notice to the EPA at least 30 days before manufacture of the new chemical substance begins. The notice must be sent in writing to: TSCA Document Control Officer (TS-790), Rm. L-100, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The date of submission will be the date on which the notice is received by the TSCA Document Control Officer. EPA will acknowledge the receipt of the notice by letter. The letter will identify the date on which the review period begins. The notice shall be submitted using EPA Form No. 7710-25 ("the PMN form"), which may be obtained from EPA by calling or writing the Environmental Assistance Division, TS-799, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC. 20460. The notice shall contain all of the information on chemical identity, impurities, trade names, production volume, uses, manufacturing sites, environmental release, and worker exposure required under § § 720.45 and 720.50 of this chapter. The following additional information shall also be included:

(i) *Type and category of notice.* The manufacturer must clearly indicate on the first page of the PMN form that the submission is a TSCA section 5(h)(4) exemption notice, and must indicate whether the notice is being submitted under paragraph (c)(1) or (c)(2) of this section.

(ii) *Production volume.* (A) Manufacturers submitting an exemption under paragraph (c)(1) of this section will be assumed, for purposes of conducting the EPA's risk assessment, to be manufacturing at an annual production volume of 10,000 kilograms. Manufacturers who intend to manufacture an exempted substance at annual volumes of less than 10,000 kilograms and wish EPA to conduct its risk assessment based upon such lesser annual production level rather than a 10,000-kilograms level, may so designate; however, manufacturers who opt to designate annual production levels below 10,000 kilograms shall not manufacture more than the designated amount of the exempted substance unless a new exemption notice for a higher (up to 10,000 kgs) manufacturing volume is submitted to, and approved by, EPA.

(B) Manufacturers submitting an exemption under paragraph (c)(2) of this section shall list the estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12-month period during the first 3 years of production.

(iii) *Exposure and release information.* The manufacturer must include a description of each type of manufacturing, processing, and use operation involving the new chemical substance, including identification of the manufacturing site and the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance may occur, the number of workers exposed and the magnitude, duration, and frequency of exposure and

environmental release, and the controls, work practices, or equipment which limit worker exposure and environmental release. Where a manufacturer provides worker exposure or environmental release control descriptions to support the exemption notice, the manufacturer must maintain those controls throughout the period of the exemption. Where the physical form of the new chemical substance contributes to the control of human exposures, (e.g., a non-volatile liquid form rather than a powder form), the manufacturer must continue manufacturing, processing, and/or using the new chemical substance in the physical form described. Where another manufacturer holds an exemption for the new chemical substance under this section, the manufacturer submitting a notice for the additional exemption under this section must also demonstrate that the additional human exposure to, and/or environmental release of, the new chemical substance resulting from its manufactured volumes will not present an unreasonable risk of injury to human health or the environment.

(iv) *Certification.* In addition to the certifications required in the PMN form, the following certifications shall be included in submissions under this section. The manufacturer must certify that:

(A) The manufacturer intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

(B) The manufacturer is familiar with the terms of this section and will comply with those terms, including the requirements to employ the controls, work practices, or equipment to control exposure to and release of the exempted substance which is described in the exemption notice.

(C) The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

(D) For substances manufactured under paragraph (c)(1) of this section, the manufacturer:

(*1*) Intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30–day review period, and will withdraw the exemption in the event that such manufacture is not commenced within that time.

(*2*) Will comply with any applicable production volume limitations in accordance with paragraph (e)(1)(ii) of this section.

(2) *Sanitized copy of notice.* (i) The manufacturer must make all claims of confidentiality in accordance with paragraph (k) of this section. If any information is claimed confidential, the manufacturer must submit a second copy of the notice, with all information claimed as confidential deleted, in accordance with paragraph (k)(3) of this section.

(ii) If the manufacturer does not provide the second copy, the submission will be considered incomplete.

(3) *Incomplete notices.* If EPA receives a submission which does not include all of the information required under paragraph (e) of this section, the submission will be determined to be incomplete by EPA. To reinitiate an exemption notice which has been declared incomplete, a manufacturer must submit a completely new exemption notice form containing all the required information; partial submissions sent to EPA to supplement notices declared incomplete will not be accepted. Photocopied pages from previously submitted exemption forms will be accepted provided that the certifications page contains an original dated signature.

(f) *Review period.* EPA will review the notice submitted under paragraph (e) of this section to determine whether the new chemical substance is eligible for the exemption. The review period will end 30 days after receipt of the notice by the TSCA Document Control Officer. Upon expiration of the 30–day review period, if EPA has taken no action, the manufacturer may consider its exemption approved and begin to manufacture the new chemical substance under the terms described in its notice and in this section.

(g) *Notice of ineligibility*—(1) *During the review period.* If the EPA determines during the review period that the new chemical substance does not meet the terms of this section, that the new chemical substance meets one or more of the exclusions set forth in paragraph (d) of this section, or that there are issues concerning toxicity or exposure that require further review which cannot be accomplished within the 30–day review period, EPA will notify the manufacturer by telephone that the substance is not eligible. This telephone notification will subsequently be confirmed by certified letter that identifies the reason(s) for the ineligibility determination. The manufacturer may not begin manufacture of the new chemical substance without complying with section 5(a)(1) of the Act.

(2) *After the review period.* (i) If at any time after the review period specified in paragraph (f) of this section, EPA obtains information through a TSCA section 8(e) report or through any other source indicating that the new chemical substance does not meet the terms of this section, or that any of the exclusions set forth in paragraph (d) of this section may be applicable, EPA shall notify the manufacturer of that substance, by certified mail, that its exemption under this section will be revoked.

(ii) The manufacturer may continue to manufacture, process, distribute in commerce, and use the substance after receiving the notice under paragraph (g)(2)(i) of this section if the manufacturer was manufacturing, processing, distributing in commerce, or using the substance at the time the notification was received if the manufacturer submits written objections to EPA within 15 days of receipt of the notification. Such written objections must state the reasons why the manufacturer believes that the substance will not present an unreasonable risk of injury to health or the environment. Manufacturers not manufacturing, processing, distributing in commerce, or using the substance at the time of the notification may not begin manufacture until EPA makes its final determination under paragraph (g)(2)(iii) of this section.

(iii) EPA will consider any objections submitted under paragraph (g)(2)(ii) of this section and will make a final determination on whether to revoke the exemption. EPA will notify the manufacturer of the final determination by certified mail within 15 days of receipt of the objections submitted under paragraph (g)(2)(ii) of this section.

(iv) Within 24 hours of receipt of a final determination from EPA that an exemption is revoked, the manufacturer of the substance for which the exemption was revoked shall cease all manufacturing, processing, distribution in commerce, and use of that substance. The manufacturer may not resume manufacture, processing, distribution in commerce, or use until it submits a premanufacture notice under section 5(a)(1) of the Act and part 720 of this chapter and the notice review period has ended.

(v) Action under this paragraph does not preclude action under sections 7, 15, 16, and 17 of the Act.

(h) *Additional information.* If the manufacturer of a new chemical substance under the terms of this exemption obtains test data or other information indicating that the new chemical substance may not qualify for

the exemption, the manufacturer must submit these data or information to EPA within 15 working days of receipt of the information. If, during the notice review period, the submitter obtains possession, control, or knowledge of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must send that information to the address listed on the notice form within 10 days of receiving the new information, but no later than 5 days before the end of the notice review period. The new submission must clearly identify the submitter and the exemption notice to which the new information is related. If the new information becomes available during the last 5 days of the notice review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(i) *Changes in manufacturing site, use, human exposure and environmental release controls, and certain manufacturing volumes.* (1) Chemical substances manufactured under this section must be manufactured at the site or sites described, under the human exposure and environmental release controls described, and for the uses described in the approved exemption. Chemical substances manufactured under paragraph (c)(1) of this section and in specific annual production volumes designated pursuant to paragraph (e)(1)(ii) of this section must not exceed the 10,000 kilograms per year volume, or the designated volume, whichever is applicable.

(2) Any person who manufactures a new chemical substance under paragraph (c)(1) or (c)(2) of this section must comply with the provisions of this section, including submission of a new notice under paragraph (e) of this section, before:

(i) Manufacturing the new chemical substance at a site that was not approved in a previous exemption notice.

(ii) Manufacturing the new chemical substance for a use that was not approved in a previous exemption notice.

(iii) Manufacturing the new chemical substance without employing the human exposure and environmental release controls approved in a previous exemption notice.

(iv) Manufacturing the chemical substance in annual production volumes above any volume specified under paragraph (e)(1)(ii) of this section.

(3) In an exemption notice informing EPA of a change in site, worker protection or environmental release controls, or use, the manufacturer is not required to provide the same information submitted to EPA in a previous exemption notice on that chemical substance. The new exemption notice, however, must indicate the identity of the new chemical substance; the manufacturer's name; the name and telephone number of a technical contact; and location of the new site, worker protection or environmental release controls, or use information. The notice must also include the EPA-designated exemption number of the previous submission and a new certification by the manufacturer, as described in paragraph (e)(1)(iv) of this section.

(j) *Customer notification.* (1) Manufacturers of new chemical substances described in paragraphs (c)(1) and (c)(2) of this section must notify processors and industrial users that the substance can be used only for the uses specified in the exemption notice. The manufacturer must also inform processors and industrial users of any controls specified in the exemption notice. The manufacturer may notify processors and industrial users by means of a container labeling system, written notification, or any other method that adequately informs them of use restrictions or controls.

(2) A manufacturer of a new chemical substance described in paragraph (c)(2) of this section may distribute the chemical substance only to other persons who agree in writing to not further distribute the substance until it has been reacted or otherwise rendered into a physical form or state in which releases and exposures above the paragraph (c)(2) eligibility criteria will not occur.

(3) If the manufacturer learns that a direct or indirect customer is processing or using the exempt substance in violation of use restrictions or without imposing prescribed worker protection or environmental release controls, the manufacturer must cease distribution of the substance to the customer or the customer's supplier immediately. The manufacturer must also report this action to EPA within 15 days under paragraph (h) of this section. Within 30 days of its receipt of the report, EPA will notify the manufacturer whether, and under what conditions, distribution of the chemical substance to the customer may resume.

(k) *Confidentiality.* (1) If the manufacturer submits information to EPA under this section which the manufacturer claims to be confidential business information, the manufacturer must clearly identify the information at the time of submission to EPA by bracketing, circling, or underlining it and stamping it with "CONFIDENTIAL" or some other appropriate designation. Any information so identified will be treated in accordance with the procedures in 40 CFR part 2. Any information not claimed confidential at the time of submission may be made available to the public without further notice.

(2)(i) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide a generic chemical name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible.

(ii) The generic name provided by the submitter will be subject to EPA review and approval in accordance with the procedures specified in § 720.85(b)(6) of this chapter. The generic name provided by the submitter or an alternative selected by EPA under these procedures will be placed on a public list of substances exempt under this section.

(3) If any information is claimed confidential, the manufacturer must submit a second copy of the notice with all information claimed as confidential deleted. EPA will place the second copy in the public file.

(l) *Determination of first manufacturer of a new chemical substance.* (1) A person who intends to manufacture a new chemical substance under paragraph (c)(1) of this section may determine whether that particular substance is already being manufactured under that section and, therefore, subject to the requirements of paragraph (e)(1)(iii) of this section, by submitting a notice on the substance under paragraph (e) of this section. EPA will inform the manufacturer within the 30-day review period whether another person is already manufacturing the substance under the exemption.

(2) Alternatively, the manufacturer may ask EPA whether another manufacturer is already producing the new chemical substance under this section. EPA will respond to this inquiry only if EPA determines that the manufacturer making the inquiry has shown a bona fide intent to manufacture in accordance with the procedures set out in 40 CFR 720.25(b)(2) through (b)(9).

(3) If EPA determines that the manufacturer has not shown a bona fide intent to manufacture the new substance under the terms of this section, EPA will promptly notify the manufacturer. The manufacturer may then submit a notice

under paragraph (e) of this section or a notice under section 5(a)(1) of the Act.

(4) If EPA determines that the manufacturer has shown a bona fide intent to manufacture the new chemical substance under the terms of this section, EPA will promptly inform the manufacturer whether the substance is being manufactured under this section. If the substance is not being manufactured under this section, the manufacturer may submit a notice under paragraph (e) of this section. If the new chemical substance is being manufactured under this section, the manufacturer may submit a notice under paragraph (e) of this section if the manufacturer can demonstrate that the additional human exposure to, and/or environmental release of, the new chemical substance resulting from its manufactured volumes will not present an unreasonable risk of injury to human health or the environment. If such demonstration cannot be made, the manufacturer must submit a notice under section 5(a)(1) of the Act or one of the other section 5 exemptions.

(m) *Exemptions granted under superseded regulations.* Manufacturers holding exemptions granted under the superseded requirements of § 723.50 (as in effect on [insert date 1 day before effective date of final rule]) shall either continue to comply with those requirements or apply for a new exemption pursuant to this section. If a new exemption for a chemical substance is granted under this exemption, the prior exemption for such substance shall be void.

(n) *Recordkeeping.* (1) Each manufacturer of a new chemical substance described in paragraph (c) of this section must maintain records of the annual production volume of the new chemical substance under the exemption and documentation of information in the exemption notice and compliance with the terms of this section. Such records must be retained at each facility owned or controlled by the exemption holder where the exempted substance is manufactured or processed. Records maintained under this paragraph must be retained for 5 years after the date of their preparation.

(2) Any person who manufactures a new chemical substance under the terms of this section must, upon request of a duly designated representative of EPA, permit such person at all reasonable times to have access to and to copy records kept under paragraph (n)(1) of this section.

(3) The manufacturer must submit the records listed in paragraph (n)(1) of this section to EPA upon written request. Manufacturers must provide these records within 15 working days of receipt of such request.

(o) *Compliance.* (1) Failure to comply with any provision of this section is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Submitting materially misleading or false information in connection with the requirements of any provision of this section is a violation of this section and therefore a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(4) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this section, or act to seize any chemical substance manufactured or processed in violation of this section, or take other action under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 1616).

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